

K083105

This summary is being submitted in accordance with the requirements of 21 CFR 807.92.

## 1. Contact Details

JUL 24 2009

Name: Anne-Marie Keenan  
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Galway, Ireland  
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Prepared: 15<sup>th</sup> June 2009

## 2. Device Name

Trade Name of Device: Kneehab XP Conductive Garment (Type 411)  
Common Name: Muscle Stimulator  
Classification Name: Powered Muscle Stimulator  
Regulation Number: 21 CFR 890.5850  
Product Code: IPF

## 3. Identification of Equivalent Legally Marketed Device

1. Name: Kneehab, Type 410  
Manufacturer: Bio-Medical Research Ltd.  
510(k) No: K024258, March 2005  
  
2. Name: System Shorts, Type 390, Model E20  
Manufacturer: Bio-Medical Research Ltd.  
510(k) No: K070142, March 2007

## 4. Description of Device

The Kneehab XP Conductive Garment is a portable, two-channel transcutaneous electrical muscle stimulator incorporating multipath®, a patented technology developed by neurotech®. This technology enables the Kneehab XP Conductive Garment to deliver highly

focused and accurate quadriceps contractions and operates by using constant current pulses to stimulate the nerves in the quadriceps area of the body. These pulses are designed to cause muscular contractions through the application of electrical stimulation to the peripheral nervous system.

The Kneehab XP pack consists of a rechargeable control unit, a left or right universally sized garment, a pack of custom adhesive electrodes, a battery charger and instructions for use. The garment is fastened around the thigh and above the kneecap and contains a connector socket into which the control unit is plugged. Power is derived from a 3.6V NiMH rechargeable battery pack that is pre-installed in the unit. A battery charger is included with the device. This device cannot be used while being charged.

All internal connections of the unit are over molded to prevent moisture ingress. The user has no access to the wiring or connectors within the garment and is unable to alter the current path. There are three treatment programs in total with duration of 20 minutes each. Program details are included in the instructions for use. For purposes of hygiene, the garment may be cleaned and instructions for device care are included in the user manual.

## **5. Statement of Intended Use/Indications for Use**

Kneehab XP applies muscle and nerve stimulation by using the principles of Neuromuscular Electrical Nerve Stimulation (NMES). NMES is the application of electrical stimulation of the peripheral nervous system to contract a muscle either through the direct activation of the motor neurons in the mixed peripheral nerve, or indirectly through reflex recruitment. Kneehab XP applied brief electrical pulses through skin surface adhesive electrodes.

The Kneehab XP conductive garment, type 411 is indicated for muscle re-education of the quadriceps, maintaining or increasing range of motion of the knee joint, prevention or retardation of disuse atrophy in the quadriceps, early post-surgical quadriceps strengthening and improved post-surgical knee stability secondary to quadriceps strengthening and increasing local blood circulation.

## **6. Technological Characteristics**

There are no new technological characteristics that could affect safety or effectiveness of the Kneehab XP Conductive Garment, Type 411 device. Substantial Equivalence has been demonstrated as part this 510k submission.

## **7. Clinical and Non-Clinical Tests**

Bio-Medical Research Ltd. ("BMR") has over 30 years experience in the research, design, manufacture and marketing of medical grade products for both muscle strengthening and pain relief. BMR has two divisions – Slendertone, which develops and markets a range of consumer health and fitness products and Neurotech, which provides a range of neuromuscular stimulators for pain management and rehabilitation. Bio-Medical Research Ltd. complies with 21 CFR 820 and is registered to I.S. EN ISO 13485:2003 Medical Device Quality Management System for the design, manufacture and distribution of electro-medical devices.

Kneehab XP Conductive Garment complies with the following electrical safety and EMC international standards:

- ❑ IEC 60601-1 (1998) + A1: 1991, A2: 1995, Medical Electrical Equipment - Part 1: General Requirements for Safety
- ❑ IEC 60601-1-2 (2001), Medical Electrical Equipment - Part 1-2: General Requirements for Safety; Electromagnetic Compatibility Requirements & Tests.
- ❑ IEC 60601-2-10 (1987) + A1: 2001 Medical electrical equipment - Part 2-10: Particular requirements for the safety of nerve and muscle stimulators

A clinical study, "The effectiveness of the Kneehab™ in strengthening the quadriceps of patients in rehabilitation after anterior cruciate ligament reconstruction", has been submitted as part of this 510k premarket notification.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Bio-Medical Research, Ltd.  
% Ms. Anne-Marie Keenan  
Parkmore Business Park West  
Galway, Ireland

JUL 24 2009

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Re: K083105

Trade/Device Name: Kneehab XP Conductive Garment, Type 411  
Regulation Number: 21 CFR 890.5850  
Regulation Name: Powered muscle stimulator  
Regulatory Class: II  
Product Code: IPF  
Dated: July 15, 2009  
Received: July 21, 2009

Dear Ms. Keenan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/cdrh/mdr/> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", with a long horizontal flourish extending to the right.

Mark N. Melkerson  
Director  
Division of Surgical, Orthopedic,  
and Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): \_\_\_\_\_

Device Name: Kneehab XP Conductive Garment, Type 411

### Indications for Use:

- Muscle re-education of the quadriceps,
- Maintaining or increase range of motion of the knee joint,
- Prevention or retardation of disuse atrophy in the quadriceps,
- Early post-surgical quadriceps strengthening and improved post-surgical knee stability secondary to quadriceps strengthening,
- Increasing local blood circulation.

Prescription Use X  
(Part 21 CFR 801 Subpart D)

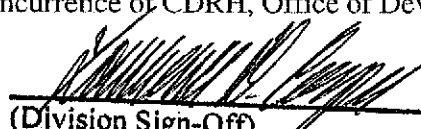
AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

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OF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)

Division of Surgical, Orthopedic,  
and Restorative Devices

510(k) Number K083105